REMARKS

In reply to the Office Action of September 21, 2004, independent claims 34, 54, and 73 have been amended to clarify the claimed invention. Dependent claims 40 and 59 have further been amended to correct a typographical error therein. Applicant hereby requests reconsideration of the application, in view of these amendments and the remarks which follow.

I. Brief Description of Currently Amended Independent Claim 34 and Original Claims 35-53

Claims 34-53 are directed to a biological suspension processing system comprising, inter alia: a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a third fluid flow path communicating with the treatment device for withdrawing another constituent of the blood from the treatment device; and at least one microelectromechanical sensor

communicating with one of the fluid flow paths for sensing either a biological or a chemical characteristic of the fluid within the flow path while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject.

IA. Mian Neither Discloses Nor Suggests the Subject Matter of Claims 34-45

Claims 34-45 stand rejected under 35 U.S.C. §102(e) as being anticipated by Mian et al. (U.S. 2001/0055812 A1). The office action states that Mian discloses the biological suspension processing system as claimed by the Applicant. More specifically, it states that "Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient."

Applicant's claimed invention is readily distinguishable from Mian and the attempted combination of various aspects of Mian as set forth by the office action. More specifically, Mian's Blood Composition Determination device has a first, second, and third mircochannels routed in a circular arrangement about a disk. (¶284) "In conjunction with the microchannel diameter information and the pattern of orientation of the

channels on the disk, pressure data can be used to determine flow rates at a particular rotational speed. This information can then be used by the microprocessor to adjust disk rotational speed to control fluid movement on the disk." (¶284). As further described in paragraph 216, the loading device may include a lancet for obtaining a small blood sample. Nevertheless, this lancet must be removed from the human subject before rotation of the disc and analysis of the sample.

In contrast, Applicant's claimed invention comprises a fluid path for actually communicating blood ("in continuing, direct, communication") from a patient to a treatment device, such as centrifuge. Therefore, as currently amended in independent claim 34, the first MEM sensor communicates with a fluid flow path to sense biological and chemical characteristics of the fluid within the flow path while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject.

Typically, this requires significant volumetric flow rates that can be up to about 50-70 ml/min or more. The microchannel system as described in Mian is grossly insufficient and impractical for such an application. In further contrast, the first MEM sensor communicates with the fluid flow paths to sense biological and chemical characteristics of the fluid within the

flow path such as red cell count, platelet count, lipid level, blood type or markers representative of pathogen presence; white cell count, red cell hematocrit and platelet density; or white cell count, packed red cell hematocrit, platelet dose, pH, or gas partial pressure while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject.

Mian is directed to an entirely different system, where very small, previously obtained, and isolated samples are processed discontinuously through microchannels. There is no actual treatment device, no fluid flow paths directly communicating between a human and the treatment device while a MEM sensor communicates with a fluid flow path to sense biological and chemical characteristics of the fluid within a flow path.

In view of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §102(e) rejection and allowance of these claims.

IB. The Kowarski-Yager Combination Does not Render Applicant's Arrangement of Claim 34 Obvious

Claim 34 also stands rejected under 35 U.S.C. §103(a) as being unpatentable over Kowarski (U.S. Patent 4,006,743) in view

of Yager et al. (U.S. 5,932,100). The office action states that "Kowarski teaches a system for continuously withdrawing blood from a patient, treating the withdrawn sample by micrdiffusion device 64, and sensing system 76 to analyze the components of the blood." Although the office action correctly states that Kowarski does not disclose a MEM sensor, it concludes that when combined with Yager, Applicant's claimed invention is rendered obvious.

Applicant respectfully submits that this Kowarski-Yager combination does not render Applicant's claimed invention obvious. In contrast to both Kowarski and Yager, Applicant's claimed invention as amended herein is directed to a system comprising a first fluid flow path in communication with the vascular system of a human subject and a treatment device, and second and third fluid flow paths in communication with a treatment device for withdrawing constituents of the blood from the treatment device. This system employs a MEM sensor for sensing either a biological or a chemical characteristic of the fluid within one of the fluid flow paths.

Kowarski instead describes a system which includes a fluid flow path 28 which generally begins at a catheter 22 (shown in Fig. 1), flows through a microdiffusion chamber system 64 (shown in Fig. 6), is positioned about the grooved member of the

milking device 36 (shown in Fig. 1), and continues within housing 30 and inserted into the port 46 of the plastic collection bag 44 to facilitate the eventual collection of withdrawn blood (shown in Fig. 1).

More specifically, the microdiffusion system, as shown in greater detail in Fig. 7 of Kowarski, includes two plastic housing sections 66 and 68. The withdrawn blood from fluid flow path 28, passes through the chamber as indicated by a direction-of-flow line 82 wherein the diffusible fraction of materials in the blood will diffuse through the membrane 80 into the chamber 74. *See* Col. 4, lns. 31-65. Accordingly, the device as described in Kowarski does not include second or third fluid flow paths in communication with a treatment device for withdrawing constituents of the blood from the treatment device as required by Applicant's independent claim 34. Any reasonable combination of Kowarski and Yager, even if possible, would not result in the claimed invention.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) obviousness rejection and allowance of these claims.

IC. The Langley-Altendorf Combination Does not Render Applicant's Arrangement of Claim 34 Obvious

Claim 34-45 and 47 also stands rejected under 35 U.S.C. §103(a) as being unpatentable over Langley et al. (U.S. Patent 5,496,265) in view of Altendorf et al. (U.S. Patent 5,726,751). Claims 47-53 further stand rejected as being unpatentable in further view of Leuenberger while claim 46 further stands rejected in further view of Antwiler (U.S. Patent 5,437,598).

The office action states that "Langley teaches a system for separating the components of blood continuously withdrawn from a donor with a centrifuge 18 into a separate container." Although the office action correctly states that Langley does not disclose a MEM sensor, it concludes that when combined with Altendorf, Applicant's claimed invention is rendered obvious.

Nevertheless, this Langley-Altendorf combination does not render Applicant's claimed invention obvious. In contrast to both Langley and Altendorf, Applicant's claimed invention as amended herein is directed to a system which employs a MEM sensor for sensing either a biological or a chemical characteristic of the fluid within one of the fluid flow paths.

In contrast and as shown in detail in Fig. 5, Langley describes a system which separates components of blood based on a predetermined input. More specifically, Langley describes a

system wherein a user input determines the treatment device parameters based on a donor's characteristics (i.e. height, weight, and sex). These characteristics are used as variables in predetermined equations to control the flow rates of the system. Therefore, the functioning of the treatment system (i.e. procedure time) is based on these manually entered donor input characteristics. *See* Col. 16, lns. 13-43 in reference to Fig. 5.

Accordingly, because the device is based on a predetermined input, the device as described in Langley does not include or support an on-line, real-time sensor communicating with a fluid flow path for sensing either a biological or a chemical characteristic of the fluid within the flow path.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) obviousness rejection and allowance of these claims.

II. Brief Description of Claims 54-72

Claims 54-72 are directed to a biological suspension processing system comprising a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the

vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a first microelectromechanical sensor communicating with said first fluid flow path for sensing an initial condition of the fluid within said first fluid flow path while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, said first sensor further generating a signal responsive to the initial condition of the fluid in said first fluid flow path; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a second microelectromechanical sensor communicating with said second fluid flow path for sensing either an in-process condition or a final product condition of the fluid within said second fluid flow path while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, said second sensor further generating a signal responsive to the in-process condition or final condition of the fluid in said second fluid flow path; and a controller adapted to receive the first and second sensor signals and to control the treatment device in response thereto.

IIA. Mian Neither Discloses Nor Suggests the Subject Matter of Claims 54-72

Claims 54-64 stand rejected under 35 U.S.C. §102(e) as being anticipated by Mian. As stated above, the office action suggests that "Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient."

Applicant's invention as claimed in Claims 54-72 is readily distinguishable from Mian and the attempted combination of various aspects of Mian as set forth by the office action. More specifically, Mian's Blood Composition Determination device has a first, second, and third mircochannels routed in a circular arrangement about a disk as described above. (¶284) As further described in paragraph 216, the loading device may include a lancet for obtaining a small blood sample. Nevertheless, this lancet must be removed from the human subject before rotation of the disc and analysis of the sample.

In contrast, Applicant's claimed invention comprises fluid paths for actually communicating (i.e., "continuing, direct communication") blood from a patient to a treatment device, such as centrifuge. As noted above, the microchannel system as described in Mian is grossly insufficient and impractical for

such an application. In further contrast, the first MEM sensor communicates with the first fluid flow path to sense an initial condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, such as red cell count, platelet count, lipid level, blood type or markers representative of pathogen presence. Data from the initial condition sensor, typically in the form of an electrical signal, is fed to the control system for purposes of controlling the treatment device. Mian does not disclose either a first MEM sensor for sensing initial conditions or a controller which controls the treatment device in response the initial data sensed by the first MEM sensor.

Moreover, in contrast to Mian, Applicant's claimed invention comprises a second MEM sensor which may sense an in-process characteristic such as white cell count, red cell hematocrit and platelet density. Data from the in-process condition MEM sensor is fed back to the control system for controlling the treatment device. Mian does not disclose such a second MEM sensor which senses an in-process condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, and Mian does not disclose a controller which controls the treatment device in response the in-process data sensed by the second MEM sensor.

Also, in contrast to Mian, the second MEM sensor may sense a final product condition, such as white cell count, packed red cell hematocrit, platelet dose, pH, or gas partial pressure. Data from this sensor may be relayed back to the controller for controlling the treatment device. Mian does not disclose a second MEM sensor which senses a final product condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, and Mian does not disclose a controller which controls the treatment device in response the final product data sensed by the second MEM sensor.

Mian is directed to an entirely different system, where very small, previously obtained, and isolated samples are processed discontinuously through microchannels. No actual treatment device, no fluid flow paths directly communicating between a human and the treatment device, no MEM sensors communicating with such fluid flow paths while a first fluid flow path is in continuing, direct communication with the vascular system of the human subject, and no controller responsive to signals from the MEM sensors to control the treatment device are shown or suggested in Mian.

In view of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §102(e) rejection and allowance of these claims.

IIB. The Langley-Altendorf Combination Does not Render Applicant's Arrangement of Claim 54 Obvious

Claim 54-64 and 46 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Langley in view of Altendorf. Claims 66-72 further stand rejected as being unpatentable in further view of Leuenberger while claim 55 further stands rejected in further view of Antwiler.

As described above, the office action states that "Langley teaches a system for separating the components of blood continuously withdrawn from a donor with a centrifuge 18 into a separate container." Although the office action correctly states that Langley does not disclose a MEM sensor, it concludes that when combined with Altendorf, Applicant's claimed invention is rendered obvious.

Nevertheless, this Langley-Altendorf combination does not render Applicant's claimed invention obvious. In contrast to both Langley and Altendorf, Applicant's claimed invention as amended herein is directed to a system which employs a MEM sensor for sensing either a biological or a chemical characteristic of the fluid within one of the fluid flow paths.

In contrast and as shown in detail in Fig. 5, Langley describes a system which separates components of blood based on a predetermined input. As described above, Langley describes a

system wherein a donor's characteristics are used as variables in predetermined equations to control the flow rates of the system. Therefore, the functioning of the treatment system (i.e. procedure time) is based on these manually entered donor input characteristics. *See* Col. 16, lns. 13-43 in reference to Fig. 5.

Accordingly, because the device is based on a predetermined input, the device as described in Langley does not include or support an on-line, real-time first or second sensor respectively communicating with a first or second fluid flow path for sensing an initial, in-process, or final product conditions as required by Applicant's claim 54. The Langley device further does not describe a controller for receiving signals from the first and second sensor for controlling the treatment device in response thereto as required by Applicant's claim 54. As discussed above, the control of the treatment device as described in Langley is based on predetermined inputs rather than the signals from a first and second sensor respectively associated with first and second fluid flow paths.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) obviousness rejection and allowance of these claims.

III. Brief Description of Claims 73-81

Claims 73-81 are directed to a biological suspension processing system comprising a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a first microelectromechanical sensor communicating with said first fluid flow path for sensing an initial condition of the fluid within said first fluid flow path while said first fluid flow path is in continuing, direct communication with the vascular system of the human subject, said first sensor further generating a signal responsive to the initial condition of the fluid in said first fluid flow path; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a second microelectromechanical sensor communicating with said second fluid flow path for sensing either an in-process condition or a final product condition of the fluid within said second fluid flow path while said first fluid flow path is in continuing, direct communication with the vascular system of the human subject, said second sensor further generating a signal

responsive to the in-process condition of the fluid in said second fluid flow path; a third fluid flow path communicating with the treatment device for withdrawing another constituent of the blood from the treatment device; a third microelectromechanical sensor communicating with said third fluid flow path for sensing a final product condition of the fluid within said third fluid flow path while said first fluid flow path is in continuing, direct communication with the vascular system of the human subject, said third sensor further generating a signal responsive to the final product condition of the fluid in said third fluid flow path; and a controller adapted to receive the first, second, and third sensor signals and to control the treatment device in response thereto.

IIIA. Mian Neither Discloses Nor Suggests the Subject Matter of Claims 73-81

Claim 73 stands rejected under 35 U.S.C. §102(e) as being anticipated by Mian. The office action suggests that "Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient."

Applicant's invention as claimed in Claims 73-81 is readily distinguishable from Mian and the attempted combination of various aspects of Mian as set forth by the office action. As described above, Mian's Blood Composition Determination device has a first, second, and third mircochannels routed in a circular arrangement about a disk. (¶284) As further described in paragraph 216, the loading device may include a lancet for obtaining a small blood sample. Nevertheless, this lancet must be removed from the human subject before rotation of the disc and analysis of the sample.

In contrast, Applicant's claimed invention comprises a fluid path for actually continuously communicating blood from a patient to a treatment device, such as centrifuge. As described above, the microchannel system as described in Mian is grossly insufficient and impractical for such an application. In further contrast to Mian, the first MEM sensor in Applicant's claimed invention communicates with the first fluid flow path to sense an initial condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject. These initial conditions include, but are not limited to, red cell count, platelet count, lipid level, blood type or markers representative of pathogen presence. Data from the initial condition sensor, typically in the form of an

electrical signal, is fed to the control system for purposes of controlling the treatment device. Mian does not disclose either a first MEM sensor for sensing initial conditions or a controller which controls the treatment device in response the initial data sensed by the first MEM sensor while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject.

Moreover, in contrast to Mian, Applicant's claimed invention comprises a second MEM sensor which may sense an in-process characteristic while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject. These inprocess characteristics include, but are not limited to, white cell count, red cell hematocrit and platelet density. Data from the in-process condition MEM sensor is fed back to the control system for controlling the treatment device. Mian does not disclose such a second MEM sensor which senses an in-process condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, and Mian does not disclose a controller which controls the treatment device in response the in-process data sensed by the second MEM sensor.

Also, in contrast to Mian, Applicant's claimed invention comprises a third MEM sensor which may sense a final product

condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject. These final product conditions include, but are not limited to, white cell count, packed red cell hematocrit, platelet dose, pH, or gas partial pressure. Data from this sensor may be relayed back to the controller for controlling the treatment device. Mian does not disclose such a third MEM sensor which senses a final product condition while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, and Mian does not disclose a controller which controls the treatment device in response the final product data sensed by the third MEM sensor.

Mian is directed to an entirely different system, where very small, previously obtained, and isolated samples are processed discontinuously through microchannels. No actual treatment device, no fluid flow paths directly communicating between a human and the treatment device, no MEM sensors communicating with such fluid flow paths while the first fluid flow path is in continuing, direct communication with the vascular system of the human subject, and no controller responsive to signals from the MEM sensors to control the treatment device are shown or suggested in Mian.

In view of the foregoing amendment and remarks, Applicant respectfully requests allowance of these claims.

IIIB. The Langley-Altendorf Combination Does not Render Applicant's Arrangement of Claim 73 Obvious

Claim 73 and 75 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Langley in view of Altendorf. Claims 75-81 further stand rejected as being unpatentable in further view of Leuenberger while claim 74 further stands rejected in further view of Antwiler.

As described above, the office action states that "Langley teaches a system for separating the components of blood continuously withdrawn from a donor with a centrifuge 18 into a separate container." Although the office action correctly states that Langley does not disclose a MEM sensor, it concludes that when combined with Altendorf, Applicant's claimed invention is rendered obvious.

Nevertheless, this Langley-Altendorf combination does not render Applicant's claimed invention obvious. In contrast to both Langley and Altendorf, Applicant's claimed invention as amended herein is directed to a system which employs a MEM sensor for sensing either a biological or a chemical characteristic of the fluid within one of the fluid flow paths.

In contrast and as shown in detail in Fig. 5, Langley describes a system which separates components of blood based on a predetermined input. As described above, Langley describes a system wherein a donor's characteristics are used as variables in predetermined equations to control the flow rates of the system. Therefore, the functioning of the treatment system (i.e. procedure time) is based on these manually entered donor input characteristics. *See* Col. 16, lns. 13-43 in reference to Fig. 5.

Accordingly, because the device is based on a predetermined input, the device as described in Langley does not include or support an on-line, real-time first, second, or third sensor respectively communicating with a first, second, or third fluid flow path for sensing an initial, in-process, or final product conditions as required by Applicant's independent claim 73. The Langley device further does not describe a controller for receiving signals from the first, second, and/or third sensors for controlling the treatment device in response thereto as required by Applicant's independent claim 73. As discussed above, the control of the treatment device as described in Langley is based on predetermined inputs rather than the signals from a first, second, and/or third sensor respectively associated with first, second, and/or third fluid flow paths.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) obviousness rejection and allowance of these claims.

Conclusion

In view of all the foregoing, reconsideration and allowance of all pending claims are respectfully requested. If any additional fee should be required, the Commissioner is hereby authorized to charge Deposit Account No. 50-1039

Respectfully submitted,

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